

# STATE OF COLORADO

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Dedicated to protecting and improving the health and environment of the people of Colorado

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Colorado Department  
of Public Health  
and Environment

## COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

### HAZARDOUS MATERIALS AND WASTE MANAGEMENT DIVISION

#### RADIATION PROGRAM

#### PENALTY POLICY

The attached policy is used in conjunction with the Radiation Program Enforcement Response Policy by the Radiation Program of the Colorado Department of Public Health and Environment, Hazardous Materials and Waste Management Division (the Division), to determine appropriate penalties for violations of radiation safety laws and regulations in Colorado, once it has been determined that a penalty will be pursued.

The procedures set out in this document are intended solely for the guidance of Division personnel. They are not intended and cannot be relied upon to create rights, substantive or procedural, enforceable by any party in litigation with the Division. The Division reserves the right to be at variance with this policy. The Division also reserves the right to change this policy at any time with appropriate publication.

Gary W. Baughman  
Division Director

5/31/11  
Date

**COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

**HAZARDOUS MATERIALS AND WASTE MANAGEMENT DIVISION**

**RADIATION PROGRAM**

**PENALTY POLICY**

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COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

HAZARDOUS MATERIALS AND WASTE MANAGEMENT DIVISION

RADIATION PROGRAM

PENALTY POLICY

I. INTRODUCTION

The Colorado Radiation Control Act, at sections 25-11-101 through 25-11-305, C.R.S., (the "Act") provides for the regulation of radioactive materials and radiation machines by the Colorado Department of Public Health and Environment (CDPHE). Through the Act, and an agreement between the Governor and the U.S. Nuclear Regulatory Commission, the CDPHE is empowered to be the sole regulator of radioactive material in Colorado. The Rules and Regulations Pertaining to Radiation Control (the Regulations), at 6 CCR 1007-1, provide the details of how radioactive materials and radiation machines are regulated in the state, and apply to all persons who receive, possess, own, acquire, use, process, store, transfer or dispose of any source of radiation in Colorado.

This penalty policy is established pursuant to the Division's penalty authority under the Colorado Radiation Control Act, §§ 25-11-101 through 305, C.R.S. (the "Act"). Section 25-11-107, C.R.S. provides, inter alia, that any person who violates the provisions of 25-11-107, C.R.S. or who violates any licensing or registration provision, rule or order under Part 1 of the Act, or any term, condition, or limitation of any license or registration certificate issued pursuant to Part 1 of the Act is subject to an administrative penalty not to exceed \$15,000.00 per day for each violation. Section 25-11-107(5), C.R.S. sets out the factors the Division shall consider when determining penalties for a violation of Part 1 of the Act. The factors are as follows:

- a. Statutory Factor (I): The seriousness of the violation;
- b. Statutory Factor (II): Whether the violation was intentional, reckless, or negligent;
- c. Statutory Factor (III): The impact on, or threat to, the public health or the environment as a result of the violation;
- d. Statutory Factor (IV): The degree of recalcitrance, if any, on the part of the violator;
- e. Statutory Factor (V): Whether the violator is a recidivist;

- f. Statutory Factor (VI): The economic benefit realized by the violator as a result of the violation;
- g. Statutory Factor (VII): The violator's voluntary, timely, and complete disclosure of the violation, if prior to the Division's knowledge of the violation, and if all reports required pursuant to state environmental control laws have been submitted as required;
- h. Statutory Factor (VIII): The violator's full and prompt cooperation with the Division following disclosure or discovery of a violation, including, when appropriate, entering into and implementing, in good faith, a legally enforceable agreement with the Division to undertake compliance and remediation efforts;
- i. Statutory Factor (IX): The existence of a comprehensive regulatory compliance program or an audit program that the violator adopted in good faith and in a timely manner, which program includes measures determined by the Division to be sufficient to identify and prevent future noncompliance; and
- j. Statutory Factor (X): Any other aggravating or mitigating circumstances.

This document sets forth the Division's policy, procedures, interpretations, and internal guidelines that shall be used in determining the amount of administrative penalties the Division shall seek in administrative compliance orders issued pursuant to Section 25-11-107, C.R.S.. Penalty assessments are made under the authority of the Executive Director of the Colorado Department of Public Health and Environment or his or her designee.

The purposes of this policy are to ensure that penalties assessed pursuant to the Colorado Radiation Control Act are assessed in a uniform and consistent manner, while allowing for a reasonable amount of flexibility and discretion; that penalties are appropriate for the gravity of the violation committed; that economic incentives for noncompliance with Colorado Radiation Control Act requirements are eliminated; that penalties are sufficient to deter persons from committing radiation safety violations; and that compliance is expeditiously achieved and maintained.

This document does not address whether the assessment of a penalty is an appropriate enforcement response to a particular violation. The Radiation Program uses its Enforcement Response Policy to evaluate enforcement options that are appropriate for addressing violations of radiation safety laws and regulations in Colorado. Rather, this document focuses on determining the proper penalty amount that the Division should seek once a decision has been made to pursue a penalty. This policy is intended to be used by the Division in calculating penalties, which the Division may unilaterally impose; however, the Division retains the enforcement discretion to impose lesser penalties as part of a negotiated settlement.

The Division may compromise, mitigate, or remit an administrative penalty imposed

pursuant to § 25-11-107(5), C.R.S. The Division may enter into a settlement agreement regarding any penalty or claim resolved under Part 1 of the Act. The settlement agreement may include the payment or contribution of moneys to state or local agencies for public health related or other environmentally beneficial purposes.

In accordance with § 25-11-107(5)(h), C.R.S, the attorney general may, at the request of the Division, institute a civil action to collect an administrative penalty imposed pursuant to § 25-11-107(5), C.R.S.

## **II. DOCUMENTATION OF INFORMATION**

To support a penalty calculation, enforcement personnel must prepare a written explanation of how the proposed penalty amount was calculated. Documentation must include all relevant information and evidence that served as the basis for the penalty amount and that were relied upon by the Division's decision-maker. This information will include information gathered during and following the inspection, as well as information provided by the licensee/registrant during any informal conferences or as part of a formal written response.

## **III. SUMMARY OF PENALTY CALCULATION PROCESS**

To determine the amount of the penalty to be assessed against a violator, all of the factors in 25-11-107(5)(c.3), C.R.S. shall be considered. Enforcement personnel will consider and evaluate the findings of the inspector, subsequent information provided by the licensee/registrant during any informal conference (if so requested) and the required written response from the regulated entity. This information shall be evaluated by considering statutory factor (I), regarding the seriousness of the violation, and statutory factor (III), regarding the impact upon or threat to the public health or environment as a result of the violation, and by considering the example violations and their associated severity levels provided in Appendix A to this Penalty Policy. Based upon its consideration of these two statutory factors and consideration of Appendix A examples, the Division shall choose an appropriate severity level and where warranted, an associated base penalty amount from the Severity Level/Base Penalty Table shown on page 6.

The base penalty amount may then be increased or decreased upon consideration of the remaining factors in § 25-11-107(5)(c.3), C.R.S. Statutory factors (II), (IV) and (V) shall be considered aggravating factors, and if determined to be applicable, an upward adjustment to the initial penalty amount shall be made. Statutory factors (VII), (VIII) and (IX) shall be considered mitigating factors and if determined to be applicable, a downward adjustment to the initial penalty amount shall be made. Statutory factor (X) allows the Division to consider other aggravating and mitigating circumstances that do not fall into one of the above categories. To determine the penalty adjustment, the

Division considers statutory factors (II), (IV), (V) and (VII) through (IX), and then adds the percentage adjustments calculated for each factor, and adjusts the base penalty amount by the resulting sum. For example, if analysis of statutory factors (II), (IV) and (V) yielded an increase of 30%, and statutory factor (VII) resulted in a decrease of 20%, the net penalty adjustment would be an increase of 10%.

If the Division has evidence that the violation continued for multiple days, an appropriate multi-day day penalty may be calculated. A penalty determination for multi-day violations will be evaluated on a case-by-case basis and is most often determined from the date of discovery.

Statutory factor (VI), the economic benefit realized by the violator as a result of the violation, is then added to the adjusted penalty to reach the final penalty amount. The economic benefit portion of the total penalty is calculated separately and is not adjusted by the aggravating and mitigating factors because its purpose is to ensure that the violator does not gain a competitive economic advantage by virtue of violating regulatory requirements. Even in cases where the presence of mitigating factors results in no base penalty assessment, a penalty sufficient to offset any economic benefit gained by the violation should be imposed (unless the violator is entitled to the immunity provided by § 25-1-114.5, C.R.S.).

When more than one violation exists, statutory factors (I) through (X) are applied on a case-by-case basis to each cited violation.

#### **IV. DETERMINATION OF SEVERITY LEVEL/BASE PENALTY**

A base penalty amount for a violation is calculated considering the statutory factors regarding the seriousness of the violation and the impact or threat to public health or the environment, and the information provided by the licensee/registrant, and information from the inspection.

- **Statutory Factor (I)**  
**Seriousness of the Violation:**

Section 25-11-107(5)(c.3)(I), C.R.S. states that the seriousness of a violation shall be considered in assessing a penalty for the violation. The seriousness of the violation shall be determined by examining the extent of deviation from a statutory or regulatory requirement or “gravity” of the violation, and the adverse impact on the Division’s ability to implement its regulatory oversight program.

To evaluate the seriousness of a violation, the Division shall examine the facts, conditions and circumstances surrounding each violation and consider the overall

behavior and actions of the violator. Division personnel shall evaluate each violation in the context of the overall scheme of the facility's compliance or non-compliance. In evaluating the extent of deviation, Division personnel should consider whether the facility complied with most or all of the requirements of the specific section of the Act, the Regulations, the license, or the registrant requirements.

- **Statutory Factor (III)**

**The impact upon or threat to the public health or the environment as a result of the violation:**

In evaluating the impact or threat to human health or the environment from radiation, and/or hazardous conditions resulting from non-compliance, the following factors shall be considered: probability that human or other environmental receptors may be exposed to radiation and/or hazardous conditions, and the potential risk of such exposure.

However, in determining the impact or threat to human health or the environment, the emphasis shall be placed on the potential for harm posed by a violation, rather than whether the harm actually occurred. The presence or absence of direct harm from a violation is something for which the violator may have no control, and, therefore, the violator should not be rewarded with potentially lower penalties simply because the violation did not result in actual harm.

1. Evaluating the impact on or threat to human health or the environment: In order to evaluate the impact upon or threat to the human health or the environment as a result of the violation, enforcement personnel should determine the relative significance of the impact or threat to human health or the environment in a particular situation.
2. Potential Risk of Exposure: When determining the potential risk of exposure or for creating a hazardous condition, enforcement personnel should weigh the harm that would result if human radiation exposure was possible or radioactive material was released into the environment. The following factors shall be considered in making that determination:
  - a) the type, amount and activity of radioactive material released or potentially released or the severity of the hazardous condition;
  - b) the activity of the source and potential for human exposure;
  - c) for machine produced radiation, the exposure duration and energy of the primary beam and potential for human exposure;
  - d) the likelihood of or fact that such radioactive material will be transported by way of environmental media, such as soil, air or groundwater; and

- e) the existence, size and proximity of potential receptor populations (e.g. local residents, fish & wildlife (including threatened or endangered species), and sensitive environmental media (e.g. surface waters and aquifers)).

DETERMINATION OF SEVERITY LEVEL/BASE PENALTY

Statutory factors I, and III (seriousness of the violation; and the impact upon or threat to the public health or the environment) are used to determine the severity level of the violation and the applicable base penalty amount in accordance with the Severity Level/Base Penalty Table below. The base penalty amount serves as a starting point when it has been determined that escalated enforcement actions are appropriate. Base penalty amounts do not necessarily result in mandatory penalties, as all statutory factors must be considered in determining a final monetary penalty amount. Examples of typical violations and their associated severity levels are provided in Appendix A to this Penalty Policy.

**SEVERITY LEVEL/BASE PENALTY**

Severity Level	Base Penalty Amount
I	\$15,000
II	\$10,000
III	\$5,000
IV	\$1,000, in cases of multiple violations
V	TBD on a case by case basis

**Severity Level I:** This is the highest severity level, and results from violations which cause immediate risk or danger to health and safety, a release to the environment of reportable quantities, substantial doses to humans, or place the Department-issued license or registration in jeopardy. Severity level I examples may also be established to serve as a regulatory deterrent.

**Severity Level II:** Not as serious as Level I, but to a lesser degree, presents any of the above risks or threats to health, safety, the environment or the license/registration.

**Severity Level III:** A serious violation, but does not present immediate risk to health, safety, the environment or the license/registration.

**Severity Level IV:** A violation, but less serious. Poses minimal risk to health, safety, the environment or the license/registration. In large numbers, this level of violation may represent a degradation in implementation of the radiation safety program.

**Severity Level V:** A minor violation that poses no immediate risk to health, safety, the environment or the license, but is a compliance issue which may lead to increased concerns or is a minor technical violation such as a record keeping error of minor impact.

Administrative penalties are assessed for Severity Level I, II, and III violations. Administrative penalties will be assessed for instances of multiple Severity Level IV violations and will be considered on a case-by-case basis for Severity Level V violations.

Note that any violation, when seen repeatedly, may be raised to a higher severity level. For example, multiple or repeated violations of lesser health and safety significance may indicate a programmatic failure to adequately oversee and implement the requirements of the radiation safety program and could result in a Severity Level III or higher violation.

## V. ADJUSTMENTS TO BASE PENALTY

Adjustments are made to the base penalty to account for the remaining statutory factors which must be considered, and to account for any economic benefit that may have been realized by the violator as a result of the violation. Following is a detailed discussion of these adjustments.

- **Statutory Factor (II)**  
**Whether the violation was intentional, reckless, or negligent**

While intentional, reckless, and negligent violations can be subject to criminal sanctions in accordance with section 25-11-107(3), C.R.S. and other statutes, there may be instances of heightened culpability where the Department chooses not to pursue a criminal action. In such instances, the penalty may be adjusted upward as described below.

1. An intentional violation means that the action causing the violation was done with purpose or with intention. Intention means the act or instance of determining mentally upon some action or result.
2. A reckless violation means that the action causing the violation was done by the violator with indifference to the consequences. For conduct to be reckless, it must be such as to demonstrate disregard or indifference to consequences, under circumstances involving danger to life or safety to others, although no harm may have actually been intended.

3. A negligent violation means that the action causing the violation was the result of an omission by the violator in doing something that a reasonable person, guided by the ordinary considerations which ordinarily regulate human affairs would do, or the doing of something which a reasonable or prudent person would not do; it is a departure from the conduct expected of a reasonable and prudent person under like circumstances.

In assessing whether the violation was intentional, reckless, and/or negligent, the following factors should be considered, as well as any other factors the Division deems appropriate:

- a) how much control the violator had over the events constituting the violation;
- b) the foreseeability of the events constituting the violation;
- c) whether the violator took or could have taken reasonable precautions to prevent the events constituting the violation;
- d) whether the violator knew or should have known of the hazards associated with the events constituting the violation; and
- e) whether the violator proceeded with actions constituting the violation with specific knowledge of whether the violator knew or should have known of the legal requirement which was violated.

It should be noted that this last factor, lack of knowledge of the legal requirement, should never be used as a basis to reduce the penalty. To do so would encourage ignorance of the law. Rather, if a violator is deemed to have acted intentionally, this will result only in an upward adjustment to the penalty.

If a violation is determined to be intentional, reckless or negligent, the base penalty may be increased by up to 50%. The Division reserves the right to aggravate the penalty beyond 50% for this factor if deemed warranted given the circumstances surrounding any given violation. As a guide, if the violation is determined to be intentional, the penalty may be increased by 50 %. If the violation is reckless, the penalty may be increased by 30 %. If the violation is determined to be negligent, the penalty may be increased by 10 %.

- **Statutory Factor (IV)**

**The degree of recalcitrance, if any, on the part of the violator:**

Recalcitrance means that the violator is resistant to authority and has not obeyed or complied with all of the requirements of the Radiation Control Act and/or other health and safety or environmental laws or regulations, thereby demonstrating a level of disregard for the statutory or regulatory requirements. To evaluate and assess the degree of recalcitrance, if any, on the part of the violator, Division enforcement personnel should again examine the violator's compliance history with all environmental laws, not just the

Colorado Radiation Control Act. If the violator has a history of recalcitrance, the base penalty shall be increased up to 50%. The Division reserves the right to aggravate the penalty beyond 50% for this factor if deemed warranted given the circumstances surrounding any given violation.

- **Statutory Factor (V)**

**Whether the violator is a recidivist:**

Recidivism means that the violator has demonstrated a pattern or tendency of intermittent non-compliance with the Colorado Radiation Control Act and/or other environmental, or health and safety laws or regulations. To evaluate and assess whether the violator is a recidivist, Division enforcement personnel should examine the violator's compliance history with all environmental laws, not just the Colorado Radiation Control Act. If the violator has a history of recidivism, the base penalty shall be increased up to 50%. The Division reserves the right to aggravate the penalty beyond 50% for this factor if deemed warranted given the circumstances surrounding any given violation.

- **Statutory Factor (VI)**

**The economic benefit realized by the violator as a result of the violation:**

The Division intends to recapture any significant economic benefit of noncompliance that accrues for a violator. The fundamental reason for this is that all economic incentives for noncompliance should be eliminated. As stated above, the penalty amount that is finally determined should never be less than the economic benefit realized as a result of the violation.

Examples of regulatory requirements for which violations are particularly likely to present significant economic benefits include, but are not limited to:

- Failure to obtain adequate financial assurance for the facility when it is required by regulation.
- Failure to obtain or hire the necessary qualified person(s) to perform specific requirements or functions required by the regulations, license, or registration.
- Failure to purchase/obtain adequate safety or monitoring equipment due to monetary constraints.

For certain Colorado Radiation Control Act requirements the economic benefit of noncompliance may be relatively insignificant (e.g., failure to submit a report on time). In the interest of simplifying and expediting an enforcement action, enforcement personnel should forego calculating the benefit component where it is determined that the amount of the component is likely to be insignificant. If there are multiple violations whose individual economic benefits are not likely to be significant but whose cumulative benefits are significant, economic benefits should be calculated for each violation.

There are two types of economic benefit of noncompliance which a violator may realize as a result of a violation: delayed costs and avoided costs. Enforcement personnel should examine both delayed costs and avoided costs to evaluate and determine the economic benefit component.

1. Calculation of economic benefit: Because the savings that are derived from delayed costs differ from those derived from avoided costs, the economic benefit from delayed and avoided costs are calculated in a different manner. For avoided costs, the economic benefit equals the cost of complying with the requirements, adjusted to reflect anticipated rate of return. For delayed costs, the economic benefit does not equal the cost of complying with the requirements, since the violator will eventually have to spend the money to achieve compliance. The economic benefit for delayed costs consists of the amount of interest on the unspent money that reasonably could have been earned by the violator during noncompliance. If noncompliance has continued for more than a year, compliance/enforcement personnel should calculate the economic benefit of both the delayed and avoided costs for each year.

In its discretion the Division may use computer models and other available methods and models to calculate the economic benefit accruing to a violator through delay or avoidance of the costs of complying with applicable requirements of the Colorado Radiation Control Act and its implementing regulations.

After calculating the total economic benefit realized from delayed costs and avoided costs, that amount will be added to the penalty amount after the final penalty amount has been calculated, including accounting for any multi-day component as described in Section VI below, to determine the total penalty amount.

2. Delayed Costs are those expenditures which have been deferred by the violator's failure to comply with the requirements. It is assumed that the violator will eventually be required to spend money to achieve compliance. Delayed costs should be calculated from the date of noncompliance to the date of compliance and assume the violator will continue operation. A delayed cost can become an avoided cost if the violator ceases operation. Examples of violations which result in savings from delayed costs include:
  - a) Failure to obtain financial assurance for the facility when required by regulation;
  - b) Failure to submit required license fees;

- c) Failure to repair or obtain required safety systems; and
- d) Failure to conduct required training.

Example calculation:

The Division has determined that for a two year period, the facility received an economic benefit by not providing the required training to facility personnel that handle radioactive material or use sources of radiation. The economic benefit for this violation has been calculated as a delayed cost for a period of two years. An assumption has been made that a cost of at least \$2,000 would have been incurred by the facility if an off-site consultant were contracted to conduct the training. Therefore, the economic benefit has been calculated as follows:

Economic Benefit = Delayed Costs = (Cost of compliance x Duration of Non-compliance) x interest rate

Delayed Cost = (\$2000 x 2 years) x 8% = \$320

Economic Benefit = \$320

3. Avoided Costs are those expenditures which are nullified by the violator's failure to comply. These are costs which will never be incurred by the licensee/registrant. Avoided costs include operating and maintenance costs. Avoided costs also would include any periodic costs, such as leasing monitoring equipment. Examples of violations which result in savings from avoided costs include:

- a. Loss, abandonment, or improper transfer or disposal of licensed material;
- b. Failure to conduct required surveys and monitoring; and
- c. Failure to conduct equipment testing and calibration at required intervals.

Example calculation:

The Division has determined that the facility has received an economic benefit by not conducting the required weekly surveys for two years. In this case, an assumption has been made that at least 15 minutes would have been necessary to perform the surveys. Further, an hourly wage of \$20 per hour for staff to perform the surveys has been used for this assessment. The economic benefit, which has been calculated as an avoided cost, has been calculated as follows:

Economic Benefit = Avoided Costs + (Avoided Costs x Interest)

Economic Benefit = (104 surveys x .25 hours per survey x \$20/hour) + (104 surveys x .25 hours per survey x \$20/hour x 8 %)

Economic Benefit = \$520 + \$42 = \$562

- **Statutory Factor (VII)**

**The violator's voluntary, timely, and complete disclosure of the violation, if prior to the Division's knowledge of the violation, and if all reports required pursuant to the state environmental control laws have been submitted as required:**

The base penalty may be reduced by 80 % or more if ALL of the following requirements are met:

1. the violator discovers a violation;
2. notifies the Division about such a violation as soon as practicable;
3. gives a voluntary and complete disclosure detailing the violation; and
4. takes actions to remedy the violation

If the violator complies with some, but not all, of the above requirements, the Division may reduce the penalty by a lesser percentage. To be voluntary, the disclosure must not already be required by any statute, regulation, order, permit, license, or other legal requirement.

- **Statutory Factor (VIII)**

**The violator's full and prompt cooperation with the Division following disclosure or discovery of a violation, including, when appropriate, entering into and implementing, in good faith, a legally enforceable agreement with the Division to undertake compliance and remediation efforts:**

If, following disclosure (by the violator) the violator acts fully and cooperatively with the Division to resolve all issues surrounding its non-compliance and any related remedial activities required to protect public health and the environment, the base penalty may be reduced by up to 25%. To obtain the benefit of this factor, the violator may also be required to fully and cooperatively enter into a legally enforceable agreement relating to compliance and remedial efforts, if deemed appropriate. A legally enforceable agreement may include a stipulated penalty provision for future violations.

- **Statutory Factor (IX)**

**The existence of a comprehensive regulatory compliance program or an audit program that the violator adopted in good faith and in a timely manner, which program includes measures determined by the Division to be sufficient to identify and prevent future non-compliance:**

A regulatory compliance program is designed to ensure that a company knows about and satisfies all regulatory requirements. Such a program should include documents, written procedures, a recognized department or division in the company, and assigned personnel whose purpose is monitoring and maintaining compliance with the applicable statutory and regulatory requirements for the management, use and disposal of radioactive materials or radiation producing machines. An audit program is an inspection/verification process that checks the company's operations on a routine basis to determine compliance with the statutory and regulatory requirements. An audit program is typically an element of a comprehensive regulatory compliance program. These programs must be legitimate and verifiable within the company and operating prior to the inspection. If such programs are operating effectively, any problems which are in existence are likely to be found. Where not already required by the regulations, the existence of such programs is evidence of good faith efforts to comply, and that the violator has taken reasonable precautions against the events that might lead to violations.

If a company satisfies the requirements of this factor by having a comprehensive regulatory compliance program not already required by the regulations prior to the inspection, the base penalty may be reduced up to 25%.

- **Statutory Factor (X)**

**Any other aggravating or mitigating circumstances.**

Any other aggravating or mitigating circumstances the Division deems relevant shall be considered. The amount of increase or reduction to the base penalty amount shall be determined by the Division on a case by case basis.

## **VI. VIOLATION DURATION**

After the base penalty has been calculated, the duration of the violation must be considered. The Colorado Radiation Control Act provides the Division with the authority to assess administrative penalties of up to \$15,000 per day of noncompliance for each violation of any licensing or registration provision, rule or order under Part 1 of the Act, or any term, condition, or limitation of any license or registration certificate issued pursuant to Part 1 of the Act. This language explicitly authorizes the Division to

consider the duration of each violation as a factor in determining an appropriate total penalty amount. Accordingly, to the extent that violations can be shown or presumed to have continued for more than one day, an appropriate multi-day penalty may be calculated. The multi-day penalty should reflect the duration of the violation at issue.

After it has been determined that an alleged violation has continued for more than one day, the next step is to determine the length of time each violation continued. Where the Division determines that a violation persists, the penalty may be calculated for a period ending on the date of compliance or the date the Compliance Order is issued, provided there is evidence to support a finding that such a violation has occurred.

## VII. MULTIPLE VIOLATIONS

In certain situations, the Division may find that a particular facility or individual has violated several different radiation control requirements. A separate penalty should be sought in a compliance order for each separate violation that results from an independent act (or failure to act) by the violator and is substantially distinguishable from any other violation in the compliance order for which a penalty is to be assessed. A given violation is independent of, and substantially distinguishable from, any other violation when it requires an element of proof not required to establish another violation. In many cases, violations of different sections of the regulations constitute independent and substantially distinguishable violations. In the case of a facility which has violated individual sections of the regulations, a separate penalty should be calculated for each violation.

It is also possible that different violations of the same section of the regulations could constitute independent and substantially distinguishable violations. While the violations are both from the same regulatory section, each requires distinct elements of proof. In this situation, two separate penalties would be appropriate. For penalty purposes, each of the violations should be assessed separately and the amounts totaled.

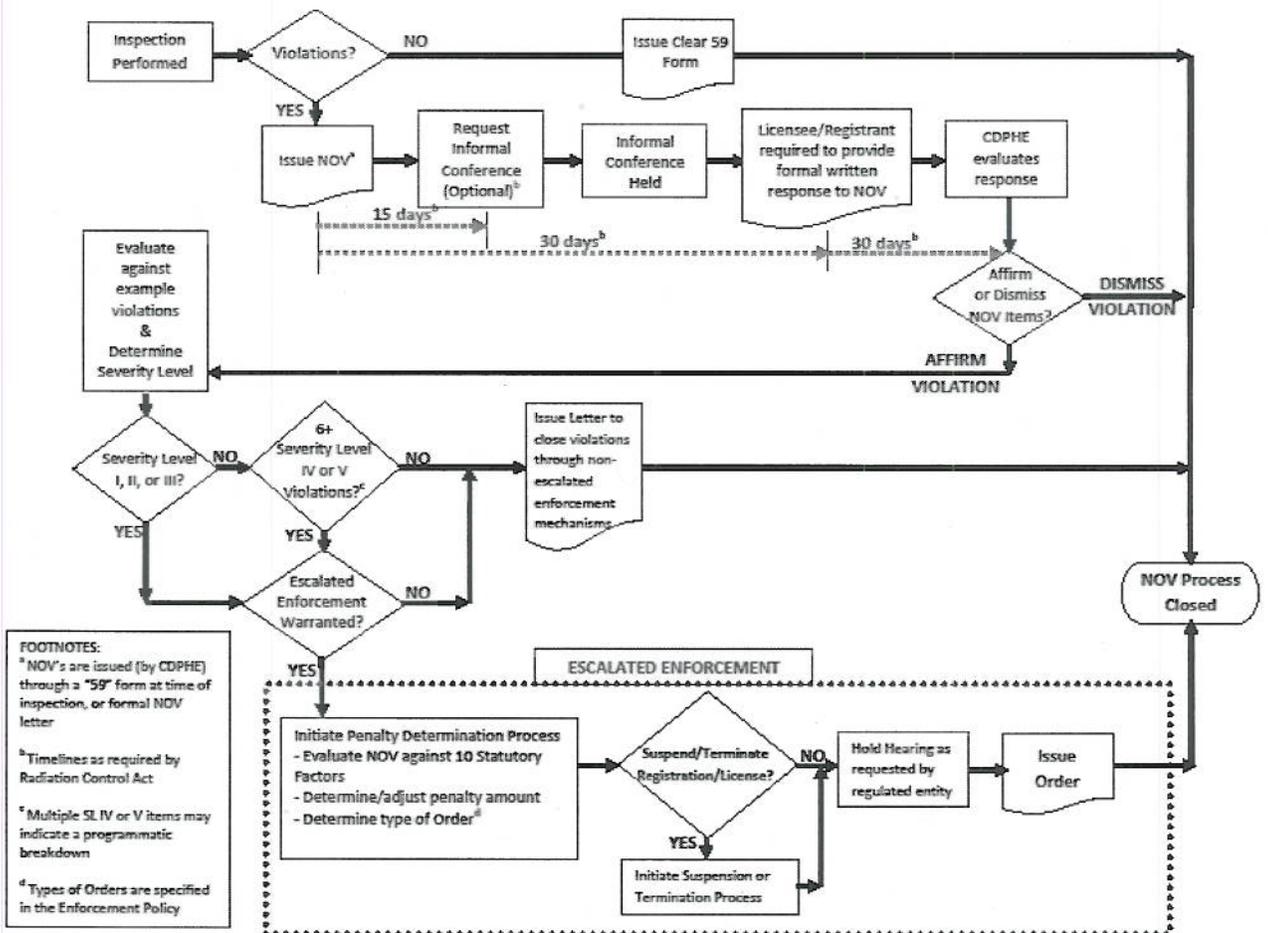
**EXAMPLE:** A licensee who possesses a radioactive source fails to perform routine leak tests of the source at the required frequency. Following an inspection, the licensee performs a leak test and discovers that the source is leaking but does not take the source out of service and does not complete the necessary notification requirements, thus violating multiple sections of Section 4.16 of the Regulations, each of which may be considered separate violations involving the same source.

Penalties for multiple counts of the same violation are appropriate when a facility violates the same requirement on separate occasions that cannot be connected as a single multi-day violation.

**EXAMPLE:** A licensee or registrant has two female workers who are required to wear dosimetry and have declared their pregnancy to the licensee or registrant in writing. The licensee or registrant provides each worker with an additional fetal dosimetry badge. At

the end of the gestation period it is determined that both workers exceeded the fetal dose limits of the regulations. This would be counted as multiple counts of the same violation since two individual workers were involved and both exceeded the regulatory limit.

The below flow chart outlines the overall enforcement and penalty process, including non-escalated and escalated enforcement.



**Appendix A  
SEVERITY LEVELS  
FOR EXAMPLE VIOLATIONS**

The severity levels of this Appendix are examples only and are not all-inclusive. The Division may determine that a particular violation is of a severity level not specifically identified. Violations and establishment of a severity level will be evaluated on a case-by-case basis and in consideration of the circumstances under which they occur. The Division reserves the right to refer to other externally published documents and guidance, and case, licensee, or registrant compliance history to establish an appropriate severity level for any particular violation.

As discussed in Section IV of this Radiation Program Penalty Policy, administrative penalties are assessed for Severity Level I, II, and III violations. Administrative penalties for lower level violations will be considered only under special circumstances as outlined in the policy.

**A. Severity Level I - Violations involving for example:**

1. An occupational radiation exposure during any year of a worker in excess of 10 rems total effective dose equivalent, 30 rems to the lens of the eye, or 100 rads to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;
2. A radiation exposure over the gestation period of the embryo/fetus of an occupationally exposed declared pregnant woman in excess of 1.0 rems total effective dose equivalent;
3. A radiation exposure during any year of an occupationally exposed minor in excess of 1.0 rems total effective dose equivalent, 3.0 rems to the lens of the eye, or 10 rems to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;
4. An annual exposure of a member of the public in excess of 0.5 rem total effective dose equivalent;
5. A release of radioactive material to an unrestricted area in annual average concentrations in excess of ten (10) times the limits for members of the public as described in Section 4.15.2.2(1);
6. Disposal of licensed material by release into sanitary sewer in quantities or concentrations in excess of ten (10) times the limits of Section 4.35;
7. Failure to meet transportation requirements that results in loss of control of radioactive material with a breach in package integrity such that the material causes a radiation exposure to a member of the public in excess of 0.5 rem;

8. Improper packaging or survey of a radioactive materials package prior to shipment that results in: surface contamination on a package in excess of fifty (50) times the U.S. Department of Transportation limit or  
  
external radiation levels emanating from a package in excess of ten (10) times the U.S. Department of Transportation Limit;
9. Radiation levels, contamination levels, or releases that exceed ten (10) times the limits specified in the license;
10. A required system or device that is designed to prevent or mitigate a serious safety event is inoperable when actually required to perform its design function, which results in serious injury or loss of life;
11. Failure to use or follow a properly prepared written directive as required by Section 7.11 or Section 24.6 that results in a death or serious injury (e.g., substantial organ impairment);
12. Failure to develop, implement, or maintain procedures for administrations requiring a written directive as required by Section 7.12 or Section 24.6; that results in a death or serious injury (e.g., substantial organ impairment);
13. Significant injury or loss of life due to a loss of control over licensed activities, including chemical processes that are integral to the licensed activity, whether radioactive material is released or not.
14. A materially false statement or record containing inaccurate or incomplete information that is provided to the Department deliberately with the knowledge that the information is incomplete or inaccurate, and the information, had it been complete and accurate at the time provided, likely would have resulted in immediate regulatory action such as an NOV or order required to ensure the public health and safety;
15. Information that the licensee or registrant has identified as having significant implications for public health and safety or the common defense and security (“significant information identified by a licensee”) that is deliberately withheld from the Department;
16. Deliberate action by licensee or registrant management to discriminate against an employee for attempting to communicate or actually communicating with the Department as specified in Part 10 of these regulations.
17. Use of a radiation producing machine for therapy on living humans before completion of acceptance testing and a radiation protection survey; or

18. Use of a radiation producing machine or device containing radioactive material that has been determined to be unsafe for use.

**B. Severity Level II - Violations involving for example:**

1. An occupational radiation exposure during any year of a worker in excess of 5 rems total effective dose equivalent, 15 rems to the lens of the eye, or 50 rems to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;
2. A radiation exposure over the gestation period of the embryo/fetus of an occupationally exposed declared pregnant woman in excess of 0.5 rem (500 mrem) total effective dose equivalent;
3. A radiation exposure during any year of an occupationally exposed minor in excess of 0.5 rem (500 mrem) total effective dose equivalent; 1.5 rems to the lens of the eye, or 5 rems to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;
4. An annual exposure of a member of the public in excess of 0.1 rem (100 mrem) total effective dose equivalent (except when up to 0.5 rem a year has been approved by the Department) and not constituting a Severity Level I violation;
5. A release of radioactive material occurs to an unrestricted area in annual average concentrations in excess of five (5) times the limits for members of the public as described in Section 4.15.2.2(1) (except when otherwise approved by the Department under Section 4.14.3);
6. Disposal of licensed material by release into sanitary sewer in quantities or concentrations in excess of five (5) times the limits of Section 4.35;
7. A failure to make an immediate notification as required by Section 4.51.1.1 or 4.52.1;
8. Failure to meet transportation requirements that results in loss of control of radioactive material with a breach in package integrity such that the material causes a radiation exposure to a member of the public in excess of 0.1 rem (100 mrem) to the whole body;
9. Improper packaging or survey of a radioactive materials package prior to shipment that results in: surface contamination on a package in excess of ten (10), but not more than fifty (50) times the US Department of Transportation limit; or  
  
external radiation levels emanating from a package in excess of five (5), but not more than ten (10) times the US Department of Transportation limit;
10. A failure to make required initial notifications associated with Severity Level I or II

Violations;

11. Radiation levels, contamination levels, or releases that exceed five (5) times the limits specified in the license;
12. A required system or device that is designed to prevent or mitigate a serious safety event is inoperable when actually required to perform its design function;
13. A substantial programmatic failure to implement written directives or procedures for administrations requiring a written directive, such as a failure of the licensee's or registrant's procedures to address one or more of the elements in Sections 7.11, 7.12 or Section 24.6, or a failure to train personnel in those procedures, that results in a misadministration (under Part 7) or reportable medical event (under Part 24);
14. The potential for a significant injury or loss of life due to a loss of control over licensed or certified activities, including chemical processes that are integral to the licensed or certified activity, whether radioactive material is released or not;
15. A materially false statement or record containing inaccurate or incomplete information that is provided to the Department deliberately with the knowledge that the information is incomplete or inaccurate, or because of careless disregard for the completeness or accuracy of the information but not amounting to a Severity Level I violation and the information, had it been complete and accurate at the time provided, likely would have resulted in regulatory action or a different regulatory position;
16. Significant information identified by a licensee/registrant potentially impacting health, safety, or the environment that is not provided to the Department because of careless disregard on the part of a licensee or registrant;
17. In a site area emergency, licensee failure to promptly (1) correctly classify the event, (2) make required notifications to responsible Federal, State, and local agencies, or (3) respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff); or
18. Deliberate exposure of a living human to radiation in the healing arts for purposes of diagnosis or therapy without a physician's written order.
19. Use of uncalibrated testing equipment for certification of radiation producing machines used for therapy on humans;

**C. Severity Level III - Violations involving for example:**

1. A release of radioactive material to an unrestricted area in annual average concentrations in excess of two (2) times the limits for members of the public as described in Section 4.15.2.2(1) except when otherwise approved by the Department under Section 4.14.3;

2. A failure to make a 24-hour notification as required by Section 4.52.2;
3. Radiation levels in an unrestricted or controlled area such that a member of the public likely would receive a dose in excess of 2 millirem in any one hour from external sources, or 100 millirem per year total effective dose equivalent, whether or not an individual is actually present in the area, and not constituting a Severity Level I or II violation;
4. A release for disposal or unrestricted use of contaminated or radioactive material or equipment that poses a realistic potential for exposure of the public to levels or doses exceeding the annual dose limits for members of the public, or which reflects a programmatic (rather than isolated) weakness in the radiation safety program;
5. Conduct of licensee or registrant activities by a technically unqualified person; or
6. A violation involving failure to secure, or maintain surveillance over licensed material that:
  - (a) involves licensed material in any aggregate quantity greater than one-thousand (1000) times the quantity specified in Appendix C to Part 4; or
  - (b) involves licensed material in any aggregate quantity greater than ten (10) times the quantity specified in Appendix C to Part 4, where there is not a functional program to detect and deter security violations that includes training, staff awareness, detection (including auditing), and corrective action (including disciplinary action); or
  - (c) results in a substantial potential for exposures or releases in excess of the applicable limits in Part 4;
7. Improper packaging or survey of a radioactive materials package prior to shipment that results in: surface contamination on packages in excess of five (5) but not more than ten (10) times the U.S. Department of Transportation limit; or  
  
external radiation emanating from a package in excess of one (1) but not more than five (5) times the U.S. Department of Transportation limit on transportation packages;
8. Any noncompliance with labeling, placarding, shipping paper, packaging, loading, or other requirements by a preparer/shipper of radioactive material that could reasonably result in the following: (a) the inability of an individual to identify the type, quantity, or form of material; (b) A failure of the carrier or recipient to exercise adequate controls; or (c) A substantial potential for personnel exposure, contamination above regulatory limits, or improper transfer of material;

9. A failure to make required initial notifications associated with Severity Level III violations.
10. Possession or use of unauthorized equipment or materials in the conduct of licensee or registrant activities which degrades safety;
11. Use of radioactive material, radioactive sources, or radiation machines on living humans where such use is not authorized;
12. Failure of a licensee or registrant to comply with Department regulations resulting in a substantial potential for exposures, radiation levels, contamination levels, or releases, (including releases of toxic material) in excess of regulatory limits;
13. A substantial programmatic failure to implement written directives or procedures for administrations requiring a written directive, such as a failure of the licensee's procedures to address one or more of the elements in Sections 7.11, 7.12 or Part 24, or a failure to train personnel in written directive procedures, that does not result in a Part 7 misadministration or Part 24 medical event.
14. A misadministration or medical event where the consequences to the patient were not limited based on a medical consultant's report, but not amounting to a Severity Level I or II violation;
15. Failure to report a medical event or misadministration.
16. A failure, during industrial radiographic operations, to have present at least two qualified individuals or to use radiographic equipment, radiation survey instruments, and/or personnel monitoring devices as required by Part 5;
17. A failure, during industrial radiographic operations, to stop work after a pocket dosimeter is found to have gone off-scale, or after an electronic dosimeter reads greater than 200 mrem, and before a determination is made of the individual's actual radiation exposure.
18. A failure to submit information to the Department regarding reciprocal recognition of licenses issued by the NRC or another Agreement State as required by Section 3.24;
19. A failure to receive required Department approval prior to the implementation of a change in licensed or registered activities that has radiological or programmatic significance, such as: (a) a change in ownership; (b) lack of an RSO or replacement of an RSO with an unqualified individual; (c) a change in the location where licensed/registered activities are being conducted, or where licensed material is being stored where the new facilities do not or have not demonstrated they meet the safety

- requirements; or (d) a change in the quantity or type of radiation sources or radioactive materials being processed or used that has radiological significance;
20. A significant failure to meet decommissioning requirements including a failure to notify the Department as required by regulation or license condition, substantial failure to meet decommissioning standards, failure to conduct and/or complete decommissioning activities in accordance with regulation or license condition, or failure to meet required schedules without adequate justification;
  21. A materially false statement or record containing incomplete or inaccurate information that is provided to the Department deliberately with the knowledge that the information is incomplete or inaccurate or because of careless disregard for the completeness or accuracy of the information but not amounting to a Severity Level I or II violation and the information, had it been complete and accurate at the time provided, likely would have resulted in a reconsideration of a regulatory position or substantial further inquiry such as an additional inspection or a formal request for information;
  22. A failure to provide significant information identified by a licensee/registrant potentially impacting health, safety, or the environment that is not provided to the Department and not amounting to a Severity Level I or II violation;
  23. In an alert condition, licensee failure to promptly (1) correctly classify the event, (2) make required notifications to responsible Federal, State, and local agencies, or (3) respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff);
  24. Failure of a radiation producing machine facility to have a proper shielding design when required;
25. Radiation producing machine violation not corrected in 30 days
25. Service Company certifies installation of radiation producing machine without machine meeting manufacturer's specification or 21 CFR Subchapter J requirements;
  26. Failure of facility to have proper protective apparel (lead aprons, gloves, etc) for staff when required by regulation or license condition;
  27. Improper disposal of radiation producing machine that could result in harm to the public or environment;
  28. Failure of x-ray machine operator to meet training and educational requirements when using a radiation machine on living humans;

29. Performance of radiation producing machine evaluations without proper registration with the Department as a Qualified Inspector (QI);
30. Performance of shielding design or radiation surveys for radiation machines at a facility without proper registration as a Qualified Expert (QE);
31. Installation or repair of a radiation producing machine without proper registration as a Service Company;
32. Use of a radiation producing machine without proper registration with the Department;
33. Use of a radiation producing machine on living humans for healing arts purposes without supervision of a physician;
34. Failure of a licensee or registrant to develop, document, and implement a formal Radiation Protection Program sufficient to ensure compliance with the Regulations.
35. Routine certification inspection for radiation producing machine is overdue by more than 120 days;
36. Use of uncalibrated testing equipment for certification of radiation producing machines used for diagnostic procedures on humans;
37. Failure of registrant or licensee to have an external or internal dose monitoring program, if required;
38. Failure of a licensee to: (a) determine the trustworthiness and reliability of individuals having unescorted access to radioactive material quantities of concern and devices; or (b) limit access to physical protection information to only those persons with an established need-to-know and who have been determined to be trustworthy and reliable;
39. Failure of a licensee to: (a) verify that a carrier uses package tracking systems, implements methods that ensure trustworthiness and reliability of drivers, maintains constant control and/or surveillance during transit, and has the capability for immediate communication to summon appropriate response or assistance, before shipping a Category 2 quantity of radioactive material, per consignment, by the carrier; or  
  
(b) initiate an investigation to determine the location of a shipment of licensed material containing a Category 2 quantity of radioactive material when the shipment does not arrive on or about the expected arrival time;
40. Failure of a licensee to use a method to disable a vehicle or trailer, in or on which a Category 1 or Category 2 quantity of radioactive material is stored, when not under direct control and constant surveillance by the licensee;

41. Failure of a licensee to establish a program to monitor and immediately detect, assess, and respond to unauthorized access to a Category 1 or Category 2 quantity of radioactive material, or a programmatic failure occurs during implementation; or
42. Failure of a licensee to verify that a recipient licensee is authorized to possess the material being transferred.

**D. Severity Level IV - Violations involving for example:**

1. A release of radioactive material to an unrestricted area at concentrations in excess of the limits for members of the public as referenced in Section 4.15.2.2 (except when otherwise pre-approved by the Department under Section 4.14.3);
2. A substantial potential for radiation doses or radioactive material releases in excess of the limits in Part 4 and not constituting a Severity Level I, II, or III violation;
3. Failure to maintain and implement a radiation safety program to keep radiation exposures as low as is reasonably achievable (ALARA);
4. Doses to a member of the public in excess of any EPA generally applicable environmental radiation standards, such as 40 CFR Part 190;
5. A failure to: (a) make the 30-day notification required by Section 4.51.1.2 or Section 4.53.2; or  
(b) make a timely written report as required by Sections 4.51.2, 4.54, or 4.56;
6. A failure to report an exceedance of the dose constraint established in Section 4.5.4 or a failure to take corrective action for an exceedance, as required by Section 4.5.4;
7. Any other matter or violation that has more than a minor safety, health, or environmental significance;
8. A violation involving an isolated failure to secure, or maintain surveillance over, licensed material that is not otherwise characterized in any aggregate quantity greater than ten (10) times the quantity specified in Appendix 4C to Part 4 provided that: (i) the material is labeled as radioactive or located in an area posted as containing radioactive materials; and (ii) such failure occurs despite a functional program to detect and deter security violations that includes training, staff awareness, detection(including auditing), and corrective action (including disciplinary action).
9. Improper packaging of radioactive material for shipment that results in a breach of package integrity where external radiation levels do not exceed the U.S. Department of

Transportation (USDOT) limit or where contamination levels do not exceed five (5) times the USDOT limits;

10. Improper survey of a radioactive materials package prior to shipment that results in surface contamination on a package that does not exceed five (5) times the USDOT limit;
11. ;
12. A noncompliance with shipping papers, marking, labeling, placarding, packaging or loading by a preparer/shipper of radioactive material not amounting to a Severity Level I, II, or III violation;
13. A failure to conduct required leakage or contamination tests on radioactive sources;
14. A failure to use properly calibrated equipment for radiation surveys or monitoring (excluding equipment used for calibration of diagnostic or therapy equipment used in the healing arts);
15. A medical misadministration involving radioactive materials that was caused by an isolated failure with limited medical consequences based on a medical consultant's report;
16. Failure to use a properly prepared written directive as required by Section 7.11 or Section 24.6; or failure to develop, implement, or maintain procedures for administrations requiring a written directive as required by Section 7.12 or Section 24.6 whether or not a medical event/misadministration occurs, provided that the failures: (1) are isolated; (2) do not demonstrate programmatic weaknesses in implementation; and (3) have limited consequences if a medical event/misadministration is involved;
17. Inaccurate or incomplete information that is provided to the Department but not amounting to a Severity Level I, II, or III violation;
18. Information that the Department requires be kept by a licensee or registrant and that is incomplete or inaccurate and of more than minor significance but not amounting to a Severity Level I, II, or III violation;
19. Employee discrimination cases involving radiation safety issues at a registered or licensed facility which, in themselves, do not warrant a higher Severity Level categorization;
20. Radiation machine facility performing healing arts on humans does not have QA/QC program for imaging system;

21. Radiation producing machine is overdue for certification by more than 60 days but less than 120 days;
22. Facility violation at a registered radiation machine facility not corrected in 30 days;
23. Failure of Qualified Inspector (QI) to adequately inspect all necessary and applicable requirements of the regulations during routine certification inspections;
24. A licensee fails to document the basis for concluding that an individual was determined to be trustworthy and reliable for the purposes of granting unescorted access to a Category 1 or Category 2 quantity of radioactive material;
25. A licensee fails to perform a complete and adequate trustworthiness and reliability determination for an individual, such that information relevant to access approval was not obtained or considered, but the individual would likely have been granted unescorted access if the required information had not been obtained or considered;
26. A licensee fails to limit approval for unescorted access with respect to a Category 1 or Category 2 quantity of radioactive material to an individual with job duties requiring unescorted access;
27. A licensee fails to maintain a list of persons approved for unescorted access;
28. A licensee fails to confirm receipt of transferred/shipped radioactive material; or
29. A licensee fails to document the prearranged plan with the local law enforcement agency or to update the prearranged plan when changes to the facility design or operation affect the potential vulnerability of sources.

**E. Severity Level V - *Minor* Violations involving for example:**

1. A violation involving an isolated failure to secure, or maintain surveillance over, licensed material in an aggregate quantity less than ten (10) times the quantity specified in Appendix 4C to Part 4;
2. Failure to secure radiation a radiation producing machine from unauthorized access or use;
3. Failure of QI/QE/Service Company to provide facility registrant a Notice of Registrant's Rights, R-65, when required;
4. Radiation producing machine is overdue for certification by more than 30 days but less than 60 days;

Failure of a Service Company for radiation producing machines to: (a) provide Operator's manual to user facility when installing new equipment; (b) report to the Department a radiation producing machine installation within 15 days;

5. or (c) register all engineers working on radiation producing machines within the State of Colorado;
6. Failure of a Qualified Inspector to submit 59-1 or 59-2 report to the Department within fifteen (15) days of completing the inspection; or